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Docket No. 54805/JPW/GJG/DRM 2-1-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Howard J. Worman and Naoto Mamiya

Serial No.: 09/407,430

Filed : September 29, 1999

For : HCV E2 PROTEIN BINDING AGENTS FOR TREATMENT HEPATITIS C VIRUS INFECTION

1185 Avenue of the Americas
New York, New York 10036
January 18, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

RESPONSE TO JULY 19, 2000 RESTRICTION REQUIREMENT AND PETITION FOR A FIVE-MONTH EXTENSION OF TIME

This is a Response to the Restriction Requirement issued July 19, 2000 in connection with the above-identified application. A response to the July 19, 2000 Restriction Requirement was originally due August 18, 2000. Applicants hereby request a five-month extension of time from August 18, 2000 to January 18, 2001. The required fee for a five-month extension of time is $945.00, for a small entity, and a check including this amount is enclosed. Small entity status has previously been established. Accordingly, a response to the July 19, 2000 Office Action is now due January 18, 2001 and this Amendment is being timely filed.

Claims 1-30 are pending in the subject application.

In the July 19, 2000 Restriction Requirement, the Examiner required restriction to one of the following allegedly distinct invention as follows:

I. Claims 1-11, drawn to a method of treating or preventing hepatitis C virus infection;

II. Claims 12-24, and 28-30, drawn to a method of identifying a compound which can inhibit the attachment of hepatitis C virus onto cells.

III. Claims 25-27, drawn to a compound and compositions containing a compound inhibiting the attachment of hepatitis C virus onto cells.

The Examiner alleged that the inventions are distinct, each from the other, because Inventions I and II are allegedly drawn to different methods having distinct process steps and endpoints to achieve different goals. The Examiner noted that methods of treating or preventing hepatitis C virus infection of Invention I are not required for methods of identifying a compound which can inhibit the attachment of hepatitis C virus onto cells of Invention II, and vice versa.

Moreover, the Examiner stated that Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP §806.05(h)). The Examiner noted that in the instant case the compound and composition of Invention III can be used in assays testing for agents inhibiting the attachment of hepatitis C onto cells.

Finally, the Examiner stated that Inventions II and III are also related as product and process use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP §806.05(h)). In the instant case, the Examiner noted that the compound and composition of Invention III can be used in methods of treating or preventing hepatitis C infection.

Alleging these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the Examiner asserted that Restriction for Examination purposes as indicated in proper.

The Examiner also stated that since claim 1, and 3-11 are generic to a plurality of patentably distinct species in claim 2, namely a) a polypeptide b) a pseudo enzyme, c) a peptidommetic compound d) a nucleic acid e) an antibody or its variant.

In response, applicants hereby elect, with traverse, Group I, claims 1-11. Within Group I, applicants elect for initial examination the polypeptide species, but look forward to a full examination of all species pursuant to MPEP §809.02(c).

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of Groups I, II, and III are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The inventions of Groups I, II, and III are all drawn to inhibition of the attachment of hepatitis C virus onto cells. Applicants therefore maintain that the Groups are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: 1) the invention must be independent and distinct, **and** 2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required, because a search of the prior art relevant to any of the claims of Group I would necessarily turn up the prior art relevant to the claims of Groups II and III, and *vice versa*. Since there is no burden on the Examiner to examine Groups I-III together in the subject application, the Examiner must examine the entire application on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121 and respectfully requests that the Examiner reconsider and withdraw the requirement for restriction. At the minimum, applicants respectfully request that claims 1-27, in their entirety, be examined in the subject application.

No fee, other than the enclosed $945.00 for a five-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

1/18/01

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